201-14612

NCIC HPV
Sent by: Mary-Beth Weaver

07/22/2003 10:34 AM

To: NCIC HPV, moran.matthew@epa.gov
cc:
cc:
Subject: HPV Challenge Program, AR-201- Registration Number:

NATALIE RUTHERFORD

07/21/2003 04:05 PM

To: chem.rtk
cc: MICHAEL MORELLI
Subject: HPV Challenge Program, AR-201- Registration Number:

FMC Corporation actively supports the EPA HPV Challenge Program, AR-201. On May 22, 2003 EPA posted comments regarding our December 30, 2002 submission of the test plan and robust summaries for the single chemical:

- Methyl 3,3-dimethyl-4, pentenoate - - CAS No. 63721-05-1

Please find attached FMC's response to EPA's comments and the revised robust summaries, with revisions in red. No changes were made to the test plan.

Please contact me if you have comments or questions regarding FMC's submission.

Sincerely,

Natalie Rutherford
APG Global Regulatory Team
Phone: (215) 299-6680
Fax: (215) 299-6468

DVE Step I - FMC Response 7-21-03.doc

DVE Step I Rev Summaries 7-21-03.doc

FMC RESPONSE TO EPA COMMENTS ON THE METHYL 3,3-DIMETHYL-4-PENTENOATE TEST PLAN

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

EPA Comment

EPA agrees with the test plan for these endpoints.

FMC Response

No additional comments.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

EPA Comment

EPA agrees with the test plan for these endpoints. However, the submitter needs to provide revised estimations based on the measured physicochemical properties.

FMC Response

Revised estimations based on the measured physiochemical properties will be provided.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

EPA Comment

Adequate data are available for the acute toxicity endpoint and gene mutations for the purposes of the HPV Challenge Program. EPA agrees with the submitter's proposal to conduct testing for chromosomal aberrations and developmental toxicity following OECD TG 473 (*in vitro* mammalian chromosomal aberration test) and 421 (reproduction/developmental toxicity screening test), respectively.

FMC Response

No additional comments.

EPA Comment

Repeated-Dose and Reproductive Toxicity. No data were submitted for these endpoints and no testing is proposed, based on the submitter's assertion that methyl 3,3-dimethyl-4-pentenoate is a closed-system intermediate.

Closed-System Intermediate Review.

EPA believes that information provided by the submitter is not sufficient to meet the criteria for claiming methyl 3,3-dimethyl-4-pentenoate as a closed-system intermediate because information on manufacture of the chemical is not provided in the test plan and information on transport of the chemical is inadequate.

FMC Response

FMC maintains its claim that this chemical is a closed system intermediate. Additional information has been provided below and added to the robust summary.

I. Site information

A. Number of sites.

EPA Comment
The test plan does not discuss the number of sites manufacturing or processing this chemical. However the Inventory Updates for 1990, 1994, and 1998 list only the site identified in the test plan as reporting for this chemical.

FMC Response

Until 2002, methyl 3,3-dimethyl-4-pentenoate was only manufactured at FMC's Baltimore site. This site no longer has the capability to produce this chemical and relies solely on an offshore producer as the source.

FMC's Baltimore location is the only site processing methyl 3,3-dimethyl-4-pentenoate. A processing description was provided in Section 1.3.2. of the robust summary.

B. Basis for "closed process" conclusion at each site.

1) Process description.

EPA Comment

No information is provided in the test plan on the manufacture of the chemical.

FMC Response

As noted above, FMC no longer manufactures methyl 3,3-dimethyl-4-pentenoate.

EPA Comment

Although the flow diagram includes an illustration of a tank truck delivering the chemical, the test plan states that the subject chemical is not transported on the site or off site.

Methyl 3,3-dimethyl-4-pentenoate is unloaded from tank trucks using nitrogen to displace the liquid chemical. The subject chemical is stored in a closed tank which is vented to a water scrubber and carbon adsorption system. The chemical is pumped through closed piping to a reactor where the intermediate chemical reacts with carbon tetrachloride to produce another chemical substance. The reactor is vented through two condensers to parallel carbon adsorbers which are open to the atmosphere.

FMC Response

Since 2002, FMC has relied solely on an offshore producer as the source of methyl 3,3-dimethyl-4-pentenoate. Methyl 3,3-dimethyl-4-pentenoate is delivered to the Baltimore site in tank trailers, as noted in the flow diagram. It is directly off loaded from the tank trailers into storage and then consumed. There is no additional transport of this chemical on site or off site.

2) Monitoring data showing no detection.

Wastewater from the facility which presumably includes water from the scrubber for the storage tank is monitored for the subject chemical. Only very low levels of methyl 3,3-dimethyl-4-pentenoate, an average of 1.55 ppm in 2002, are found in the wastewater from this process. These trace amounts are subsequently removed by a carbon treatment bed at a very high efficiency rate.

Workplace air monitoring was conducted at 20 sampling locations in 1987. The chemical was detected in two air samples at levels of 1.0 ppm and 0.8 ppm. The chemical was not detected in samples from other locations. The limit of detection at the time of sampling was 0.5 ppm.

C. Data on "presence in distributed products."

EPA Comment

The test plan states that the chemical is not present in any finished goods products manufactured from the subject chemical intermediate. No basis is provided for this statement.

FMC Response

Methyl 3,3-dimethyl-4-pentenoate is reacted to greater than 99% conversion in the Step 2 DV Ester process. Residual methyl 3,3-dimethyl-4-pentenoate is removed with waste streams. This chemical is not included on Confidential Statements of Formula for end use products, including Permethrin Technical (279-3013).

II. Information on transport (mode, volume, controls, etc)

EPA Comment

The test plan states that the subject chemical is not transported on the site or off the site. However, the flow diagram shows delivery by tank truck and preceding statements indicate that the subject chemical is unloaded from tank trucks using low pressure nitrogen displacement.

FMC Response

Since 2002, FMC has relied solely on an offshore producer as the source of methyl 3,3-dimethyl-4-pentenoate. Methyl 3,3-dimethyl-4-pentenoate is delivered to the Baltimore site in tank trailers, as noted in the flow diagram. It is directly off loaded from the tank trailers into storage and then consumed. There is no additional transport of this chemical on site or off site.

III. A data search showing that the chemical is not present in other end products.

Results from a search of the Chemical Abstracts On-Line Database indicate that the chemical is not present in any end products.

The chemical is not included in any Confidential Statement of Formula for the technical materials which use chemicals produced from the chemical at the identified site.

Ecological Effects (fish, invertebrates, and algae)

EPA Comment

The submitted data for acute fish toxicity are inadequate. The Henry's law constant and chemical structure suggest that this chemical is volatile. The submitted fish study was conducted using nominal concentrations in which the chemical's volatility was not accounted for during the test. The submitter needs to provide a rationale as to why the submitted data using nominal concentrations are adequate taking into account the results from the proposed physicochemical testing. Any testing conducted needs to use a closed system with no head space and mean measured concentrations. EPA agrees that testing is needed for aquatic invertebrates and algae with measured concentrations.

FMC Response

FMC agrees that methyl 3,3-dimethyl-4-pentenoate is volatile. The vapor pressure value at 20°C, based on two studies, is between 1.4 and 2.3 mm Hg (187 - 307 Pascals). The water solubility results will not be available until 2004, however, as this chemical is a polar molecule, its water solubility is expected to be relatively high. In addition, since this material is a methyl ester, it will be subject to hydrolysis, especially under basic pH conditions. With this in mind, the open system used for testing the toxicity of methyl 3,3-dimethyl-4-pentenoate to sheepshead minnow in study number ACT 015.11-01, is a closer representation of the potential real-life toxicity of the compound to fish. Using a closed, continuous flow-through system to test the aquatic effects of a volatile compound would certainly give a more accurate representation of the *intrinsic* toxicity of the compound, but the results of such a test would not represent a real-life scenario. Therefore, FMC believes that the open system results are adequate, unless the results of the physicochemical testing indicate otherwise.

It is also important to note that methyl 3,3-dimethyl-4-pentenoate could only contaminate water bodies, and hence aquatic organisms, via a spill during transport. Methyl 3,3-dimethyl-4-pentenoate is delivered to the Baltimore site in tank trailers. Once the material is on site, there are safeguards in place that would identify and remediate a spill such that it would not reach a waterway. It is unloaded into storage in a diked area that would contain any material spilled. It is then consumed in the DV Ester process from which wastewater streams are monitored. Only very low levels of this chemical, an average of 1.55 ppm in 2002, are found in the wastewater and these trace amounts are subsequently removed by a carbon treatment bed at a very high efficiency rate.

FMC RESPONSE TO EPA COMMENTS ON THE
METHYL 3,3-DIMETHYL-4-PENTENOATE ROBUST SUMMARIES

Health Effects

EPA Comment

Genetic Toxicity (Gene Mutations). The omitted information in the robust summary for the bacterial mutation test included the type of positive controls used and the criteria for positive results.

FMC Response

This information has been added to the robust summary.